REMARKS

New claims 34-43 were withdrawn from consideration on the grounds that prior claims 21-33 were directed to a method of contraception and not to preventing uterine bleeding incident to such a method. Reconsideration of the withdrawal is respectfully requested because the prior claims specifically recited that "the amount of the agent which exhibits progestogenic activity is effective to prevent, ameliorate or eliminate the bleeding side effects of the Selective Estrogen Receptor Modulator." Accordingly, both sets of claims are directed to a method of contraception and preventing uterine bleeding incident thereto.

Claim 34 is proposed to be amended to more particularly state the nature of the effective amount and that the method is for a female receiving contraception. Since these changes are for clarity only, the scope of the claim is not being changed.

Consideration of claims 34-42 and entry of this amendment is respectfully requested.

The claims have been amended above to delete reference to prevention for the purpose of eliminating the rejection under 35 U.S.C. § 112, second paragraph and withdrawal thereof is respectfully requested. Claims calling for ameliorating or eliminating the side effect are sufficient to protect the instant invention.

The specification was objected to under 35 U.S.C. § 112, first paragraph, as allegedly failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure and claims 21, 25, "25" (sic) and 28-33 were rejected on the same grounds on Office Action page 4 while claims 21-33 were rejected on the same grounds on Office Action page 7. Reconsideration (and in the

event the objection and rejections are not withdrawn, clarification) is respectfully requested.

While the Office Action refers to the *Wands* factors for assessing "undue experimentation", it is respectfully pointed out that consideration of those factors is not necessary until the Examiner has made a *prime facie* showing of non-enablement and that has not occurred here.

It is well established that

> ". . . a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support" *Fiers v. Revel*, 25 USPQ2d 1601, 1607 (Fed. Cir. 1993)(emphasis in original).

The instant specification "contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented." When there is an assertion of lack of enabling support, it is incumbent on the Examiner

> "to explain *why* it doubts the truth or accuracy of any statement in the supporting disclosure and to backup assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there is no need for the applicant to go through the trouble and expense of supporting his presumptively accurate disclosure". *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)(emphasis in original).

The presumptive correct specification here states that SERMs are known and have been used for contraceptive purposes and that they have the side effect of bleeding. The presumptive correct specification also states that agents which exhibits progestogenic activity are known. There is no "acceptable evidence or reasoning which is inconsistent

with the contested statement" of record here. Only conclusory statements such as "the pharmaceutical arts is unpredictable", are advanced. However, if the objection and rejection were based on the "prevention" aspect of the claims, then the foregoing amendment has rendered them moot.

It is asserted that "[a]pplicant fails to set forth the criteria that defines that would be a 'Selective Estrogen Receptor Modulator'" on page 3 but then inconsistently says on page 11 that rejection is not based on any failure to "grasp the SERM nature." Moreover, the record shows that SERM is a term of art and not a functional description of a material requiring experimentation to determine if a given compound meets that functional description.

It is also asserted that "[a]pplicant fails to set forth the criteria that defines . . . an 'agent which exhibits progestogenic activity (which) is effective to modulate the side effects of the Selective Estrogen Receptor Modulator.'" This, however, is not what is being claimed. The claims call for an "agent which exhibits progestogenic activity" and then recite that the agent is used in an amount effective to modulate the side effects of the SERM. Where is the reasoning or evidence to show the artisan would not know what is an "agent which exhibits progestogenic activity"?

The fact that the terms are ones of art renders the assertions made about the use of functional language at the point of novelty irrelevant. Functional language has not been employed.

It is respectfully submitted that the foregoing is sufficient to overcome the objection and rejections. Even if it were not, the issue has already been decided in the applicants favor. Thus, the Examiner made the same rejection citing *Wands* in the "Examiner's Answer" during the appeal proceeding for the parent application, application serial no. 09/059,476, of the present application, which has exactly the same

specification as the present specification. The claims of the parent application were directed to (i) an improvement of the method of preventing hormonal dependent breast cancer by coadministering a SERM and an agent which exhibits progestogenic activity to modulate the side effects of the SERM; and (ii) a kit comprising a SERM and a progestogenically active compound. Remanding the case, the Board of Patent Appeals and Interferences (the "Board") directed the Examiner to consider the court's opinion in *Enzo Biochem. Inc. v. Calgene, Inc.*, 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999). As a result of such consideration, the rejection was withdrawn and all the claims were allowed.

Even if it were appropriate to consider the *Wands* factors (which is denied), they establish enablement without undue experimentation. SERMs are known as is their use for contraceptive purposes and bleeding side effect. The agents which exhibits progestogenic activity are also known. Hence, the only experimentation necessary concerns the amount of the progestogenic agent. Determining how much is appropriate is facile and is routine. The skilled artisan is clearly capable of simply administering the agent and observing the result. With regard to the issues of amount of direction or guidance presented and predictability, "[i]t is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art [and] a sufficient disclosure [can be provided] either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed." *Enzo Biochem*, supra. It is here.

The present specification provides many examples of known SERMs (*see* page 5, line 6 through page 7, line 10) as well as their known use in treating or controlling an estrogen sensitive conditions, such as contraception (*see* page 4, line 23 through page 5, line 5). The specification clearly states, starting at page 7, line 11, that "[t]he SERM aspect of the present invention is similar to the previous use of such

materials for the treatment of estrogen dependent or other medical conditions. *Thus, not only may any known SERM be employed, but also the dosage amount and mode of administration heretofore employed can also be employed."* (emphasis added)

Likewise, the present specification discloses the clear criteria for progestogenically active compounds and their uses with plenty of example compounds and sufficient working examples (*see* page 7, line 30 through page 9, line 24; and Examples starting at page 11).

Thus, the present specification is sufficient to teach those of ordinary skill in the art how to make and use the invention as claimed. Accordingly, the objection to the specification and rejection of claims under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure should be withdrawn.

Claims 21-33 are rejected twice under 35 U.S.C. § 112, second paragraph, for being indefinite. The first of these rejections concerns the term "Selective Estrogen Receptor Modulator" and "agent which exhibits progestogenic activity (which) is effective to modulate the side effects of the Selective Estrogen Receptor Modulator". The comments above show that the terms actually used in the claims are definite and well known to those of ordinary skill in the art. The second of these rejections was based on the now cancelled term "preventing" Withdrawal of the rejections is respectfully requested..

Claims 21-33 were rejected under 35 U.S.C. § 103 as being allegedly unpatentable over *Jones et al.* (U.S. Patent No. 4,133,814; "*Jones*"); *Basu* (*Jap. J. Exp. Med.*, 1973, 43(1):9-15; "*Basu*"); *Shane et al.* (*Fertil. Steril.*, 1978, 29(6):692-4; "*Shane*"), in view of *Merck Manual*. The rejection is respectfully traversed.

It has been acknowledged that the references fail to teach or suggest the concomitant employment of the two agents, the administration levels, and bleeding amelioration. To overcome these deficiencies, it is noted that "[i]t is generally considered prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose." This observation presupposes that a composition is being claimed and that it was known to use progestogenic agent to effect the bleeding side effect of the SERM. But a method is being claimed and there is nothing in the record to suggest that it was known to progestogenic agent is known to effect the bleeding side effect of the SERM in any way. Indeed, of women receiving progestin only contraception, about one-third stop because of unwanted bleeding.

It is respectfully submitted that the prior art rejection is clearly based on speculation in the face of an absence of a factual basis. For instance, observing that methods of contraception have been occasioned by bleeding may inherently provide a reason for "something" to be done, it does not provide any factual basis for what should be done.

All cited prior art references merely teach the use of the disclosed compounds for contraceptive purposes, but do not teach or even suggest, each alone or in combination, an improvement of such a use of the compounds or methods of ameliorating or eliminating side effects, such as uterine bleeding, that accompany the contraceptive use of SERMs. None of the references motivates one skilled in the art to combine them to realize the invention recited in the claims.

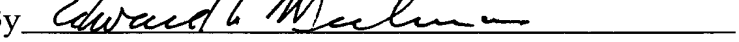
It is respectfully submitted that the rejection under 35 U.S.C. § 103 should be withdrawn.

Applicants believe that all claims are now in condition for allowance and the early issuance of a Notice of allowance is respectfully requested.

Should any fees not submitted be required, please charge such fees to Deposit Account No. 50-2215.

Dated: December 30, 2004

Respectfully submitted,

By 

Edward A. Meilman
Registration No.: 24,735
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
1177 Avenue of the Americas
New York, New York 10036-2714
Tel.: (212) 835-1400
Attorney for Applicant